K112885 (pg 1/2)

DEC 19 2011

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

zimmer

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen H. McKelvey Senior Project Manager, Trauma Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 371-8760
Date:	December 19, 2011
Trade Name:	*Zimmer*® Plates and Screws System (ZPS) – Screws only
Common Name:	Temporary Internal Fixation Devices
Classification Names and References:	Single/multiple component metallic bone fixation appliances and accessories – 21 CFR 888.3030, Smooth or threaded metallic bone fixation fastener – 21 CFR 888.3040
Predicate Devices:	Synthes 1.5mm Mini Fragment LCP System (K090047), Synthes Ti Alloy 2.0mm Cortex Screw (K952272), Zimmer Universal Locking System (K063303, K060710, K082527), Synthes 6.5mm Cancellous Screws (K061621), Pioneer Cannulated Screw System (washer - K003496) and DePuy ACE Composite Locking Nut (K983265).
Device Description:	Temporary internal fixation devices, such as the ZPS screws, are designed to stabilize fractures during the normal healing process.
Intended Use:	Temporary internal fixation devices are designed to stabilize fractures during the normal healing process.
Comparison to Predicate Device:	The ZPS Screws are similar in intended use, screw diameter, thread and drive types, and performance characteristics to the predicate devices. The proposed screws are provided sterile vs. non-sterile.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

- **Sterilization Validation** - To demonstrate that at a minimum gamma dose of 20kGy the devices can be terminally sterilized to a SAL of 10^{-6} or better.

- **Shelf Life** - Accelerated aging showed that the product has a shelf life of 10 years.

- **Sterile Packaging** - To withstand normal distribution and storage conditions and maintain the sterile barrier properties throughout the specified product shelf life.

- **Biocompatibility** - Biocompatibility testing on the screw material was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.

Providing these screws pre-sterilized did not change the intended use or the fundamental scientific technology of any of the devices. Each sterile device uses the same operating principle and incorporates the same basic labeling.

The results of either engineering evaluations and/or non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Engineering evaluations included any differences between screw diameters, partial thread vs. full threads, starting load, material strength and the differences between the drive types. Screw testing/analysis performed included; cross-sectional analysis, fatigue failure, insertion torque and torque to failure.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer Inc.
% Stephen H. McKelvey
Senior Project Manager, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, IN 46581-0708

DEC 19 2011

Re: K112885
Trade/Device Name: Zimmer® Plates and Screws System (ZPS) – Screws Only
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. McKelvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112885 (pg 1/1)

Device Name:

Zimmer® Plates and Screws System (ZPS) – Screws only

Indications for Use:

Temporary internal fixation devices are designed to stabilize fractures during the normal healing process.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

For Mark Melkerson
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112885